

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
(REV. 2-2005)TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER

PB60212-3USW

U.S. APPLICATION NO. (If known, see 37.CFR 1.5)

10/552982

INTERNATIONAL APPLICATION NO.  
PCT/EP04/004121INTERNATIONAL FILING DATE  
April 16, 2004PRIORITY DATE CLAIMED  
April 17, 2003

## TITLE OF INVENTION

COMBINATIONS OF PAROXETINE AND 2-(R)-(4-FLUORO-2-METHYL-PHENYL)-4-(S)-((8AS)-6-OXO-HEXAHYDRO-PYRROLO'1,2-A'-PYRAZIN-2-YL)-PIPERIDINE-1-CARBOXYLIC ACID'1-(R)-(3,5-BIS-TRIFLUOROMETHYL-PHENYL)-

## APPLICANT(S) FOR DO/EO/US

MELOTTO, Sergio; CORSI, Mauro; CARLETTI, Renzo

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

## Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. EV 332063889 US
23. ☒ Other items or information:
  - a) PCT Cover Page

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <div style="font-size: 2em; font-weight: bold; text-align: center;">10/552982</div>		INTERNATIONAL APPLICATION NO. PCT/EP04/004121		ATTORNEY'S DOCKET NUMBER PB60212-3USW	
The following fees are submitted:				CALCULATIONS      PTO USE	
24. <input checked="" type="checkbox"/> Basic national fee .....		\$300		\$ 300.00	
25. <input checked="" type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4). ....		\$100		\$ 200.00	
All other situations. ....		\$200			
26. <input checked="" type="checkbox"/> Search fee .....					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....		\$100			
International Search Report prepared and provided to the Office .....		\$400			
All other situations. ....		\$500		\$ 400.00	
TOTAL OF 24, 25 and 26 =				\$ 900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0	/50 =	0	x	\$250.00
				\$ 0.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	14 - 20 =	0	x	\$50.00	\$ 0.00
Independent claims	2 - 3 =	0	x	\$200.00	\$ 0.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> +				\$360.00	\$ 0.00
TOTAL OF ABOVE CALCULATIONS =				\$ 900.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ 0.00	
SUBTOTAL =				\$ 900.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ 0.00	
TOTAL NATIONAL FEE =				\$ 900.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +				\$ 0.00	
TOTAL FEES ENCLOSED =				\$ 900.00	
				Amount to be \$	
				Amount to be \$	
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.					
b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>07-1392</u> in the amount of <u>\$900.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>07-1392</u> . A duplicate copy of this sheet is enclosed.					
d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
<div style="font-size: 3em; font-weight: bold;">23347</div>				SIGNATURE <u>Lorie Ann Morgan</u> NAME <u>38,181</u> REGISTRATION NUMBER	

<b>CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)</b>			Docket No. PB60212-3USW	
Applicant(s): Melotto, S., et al.				
Application No. To Be Assigned	Filing Date Concurrently Herewith	Examiner	Customer No. 2534	Group Art Unit <b>10/552982</b>
Invention: COMBINATIONS OF PAROXETINE AND 2-(R)-(4-FLUORO-2-METHYL-PHENYL)-4-(S)-((8AS)-6-OXO-HEXAHYDRO-PYRROLO'1,2-A'-PYRAZIN-2-YL)-PIPERIDINE-1-CARBOXYLIC ACID'1-(R)-(3,5-BIS-TRIFLUOROMETHYL-PHENYL)-ETHYL-METHYLAMIDE F. TREATMT. OF DEPRESSION/ANXIETY				
<p>I hereby certify that the following correspondence:</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"><p>National Phase Application w/accompanying papers</p></div> <p style="text-align: center;"><i>(Identify type of correspondence)</i></p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on</p> <p style="text-align: center;"><u>October 12, 2005</u> <i>(Date)</i></p> <div style="text-align: right; margin-top: 20px;"><p>Valerie L. Phillips <i>(Typed or Printed Name of Person Mailing Correspondence)</i></p><p><u>Valerie L. Phillips</u> <i>(Signature)</i></p><p><b>EV332063889US</b> <i>("Express Mail" Mailing Label Number)</i></p></div>				